

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re: Sean McFerran Confirmation No.: 7830
Serial No.: 10/667,056 Examiner: Phillip A. Gray
Filing Date: September 22, 2003 Group Art Unit: 3767
Docket No.: 1001.1708101 Customer No.: 28075
For: MICROCATHETER WITH SLEEVED GUIDEWIRE PORT

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Commissioner for Patents
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APPEAL BRIEF UNDER 37 C.F.R. § 41.37

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By Kathleen L. Boekley
Kathleen L. Boekley

Dear Sir:

Pursuant to 37 C.F.R. § 41.37, Appellant hereby submits this Appeal Brief in furtherance of the Notice of Appeal filed on February 12, 2007, and of the Notice of Panel Decision from Pre-Appeal Review dated Mailed April 25, 2007. Appellant authorizes the fee prescribed by 37 C.F.R. § 41.20(b)(2) in the amount of \$500.00 to be charged to Deposit Account No. 50-0413. Permission is hereby granted to charge or credit Deposit Account No. 50-0413 for any errors in fee calculation.

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I. REAL PARTY IN INTEREST

The real party in interest is the assignee of record, Boston Scientific Scimed, Inc., a corporation organized and existing under and by virtue of the laws of Minnesota, and having a business address of One SciMed Place, Maple Grove, MN 55311-1566. An assignment from the inventor, Sean McFerran, conveying all right, title and interest in the invention to SciMed Life Systems, Inc. has been recorded at Reel 014533, Frame 0283; and a change of name from SciMed Life Systems, Inc. to Boston Scientific Scimed, Inc. has been recorded at Reel 018505, Frame 0868.

II. RELATED APPEALS AND INTERFERENCES

There are no other known appeals or interferences that will directly affect, or be directly affected by, or have a bearing on the Board's decision in this appeal.

III. STATUS OF CLAIMS

Claims 13 and 15-20 are pending in the application. Claims 1-12 and 14 have been cancelled from the application.

Claims 13 and 15-17 stand finally rejected under 35 U.S.C. § 103(a) as being unpatentable over Alchas, U.S. Patent No. 5,030,210, in view of Person et al., U.S. Patent No. 5,807,349.

Claims 18-20 are indicated as allowable in the Final Office Action of September 12, 2006.

The rejection of claims 13 and 15-17 of the application is currently being appealed.

IV. STATUS OF AMENDMENTS

No amendments were filed subsequent to final rejection.

V. SUMMARY OF CLAIMED SUBJECT MATTER*

The invention relates generally to a medical catheter that can be used in intravascular applications such as delivering therapeutic agents or devices to a site within a body lumen, the catheter having a guidewire port having a valve that provides rapid exchange capability to the catheter while providing a relatively fluid tight seal when the guidewire is not present.

Turning now to independent claim 13, which is directed to a single lumen microcatheter (page 5, lines 7-9, Figure 1 at numeral 10), comprising an elongate shaft having a distal end and a proximal end (page 5, lines 14-16, Figure 1 at numerals 12 (elongate shaft), 14 (proximal end) and 16 (distal end)), the elongate shaft having an outer surface and an inner surface, the inner surface defining a lumen extending through the elongate shaft (page 5, line 22, Figure 2 at numeral 30); an elongate guidewire port positioned proximal of the distal end of the elongate shaft (page 8, lines 3-8, Figure 6 at numeral 44), the elongate guidewire port extending from the inner surface of the elongate shaft to the outer surface of the elongate shaft (Figure 7 at numeral 44); and a polymer sheath disposed over the elongate guidewire port (page 8, lines 20-21, Figures 6 and 7 at numeral 50), the polymer sheath having an inner surface and an outer surface, the polymer sheath including a passage comprising an angled slit extending radially through the polymer sheath at an angle such that the slit has a depth that is greater than a thickness of the polymer sheath (Figure 7 at numeral 56), the slit disposed parallel to a longitudinal axis of the

* The references to the specification and drawings provided herein are exemplary, and are not deemed to be limiting. For simplicity and because the application was restricted to the embodiment of Figures 2 and 3, the references to the specification and drawings are primarily directed towards Figures 2 and 3 and the corresponding description in the specification, but this is not meant to be limiting as support may be found throughout the specification and in many of the Figures.

elongate shaft (Figure 6 at numeral 56), the passage in communication with the elongate guidewire port, wherein the passage is configured to permit guidewire access through the elongate guidewire port while remaining substantially fluid tight in use when no guidewire is provided through the passage (page 9, lines 14-19).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

1. Whether claims 13 and 15-17 are unpatentable under 35 U.S.C. § 103(a) over Alchas, U.S. Patent No. 5,030,210, in view of Person et al., U.S. Patent No. 5,807,349.

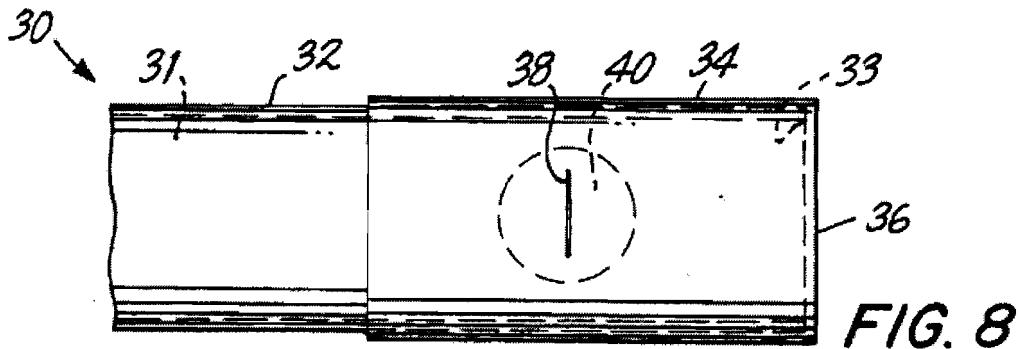
VII. ARGUMENT

A. CLAIMS 13 AND 15-17 ARE PATENTABLE UNDER 35 U.S.C. § 103(A) OVER ALCHAS, U.S. PATENT NO. 5,030,210, IN VIEW OF PERSON ET AL., U.S. PATENT NO. 5,807,349.

1. *Prior art references must teach or suggest all of the claimed limitations.*

To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). Independent claim 13 recites, in part, “an elongate guidewire port,” which, contrary to the assertion of the Examiner, is not taught by the cited prior art.

In the Final Office Action of September 12, 2006, the Examiner argues that Alchas discloses an elongate guidewire port (40). However, after careful review of Alchas, this does not appear to be true. There is nothing in Alchas to suggest that opening 40 is elongate. For example, there is nothing in the specification of Alchas to suggest that opening 40 is elongate and Figures 8 and 10, the only two views to show a top view of opening 40, depict opening 40 as perfectly circular. Figure 8 is reproduced here:



One can see that opening 40, which the Examiner asserts anticipates the “elongate guidewire port” of claim 13, is perfectly circular.

Appellant had argued this point in the response of June 21, 2006 to the March 31, 2006 Office Action. The Examiner responded to Appellant’s arguments by first pointing out, quite correctly, that “the claim limitations are to be given their broadest reasonable reading.” Final Office Action of September 12, 2006. However, the Examiner went on to assert, incorrectly and without a scintilla of reasoning to support the assertion, that “the prior art of record does indeed disclose an “elongate guidewire port” since the element (40) is fully capable of all structural, functional, spatial and operational limitations associated with the claim language of “Elongate guidewire port.” As a preliminary matter, this is not the test of whether a reference discloses a claim element. The test is that “a reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill in the art.” *Merck & Co. v. Biocraft Laboratories*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), *cert. denied*, 493 U.S. 975 (1989). With regard to a figure or a picture, “drawings and pictures can anticipate claims if they clearly show the structure which is claimed. *In re Mraz*, 455 F.2d 1069, 173 USPQ 25 (CCPA 1972). In this case, the figures of Alchas do not clearly show an elongate guidewire port. Quite to the contrary, the figures of Alchas clearly show a circular opening. With regard to the

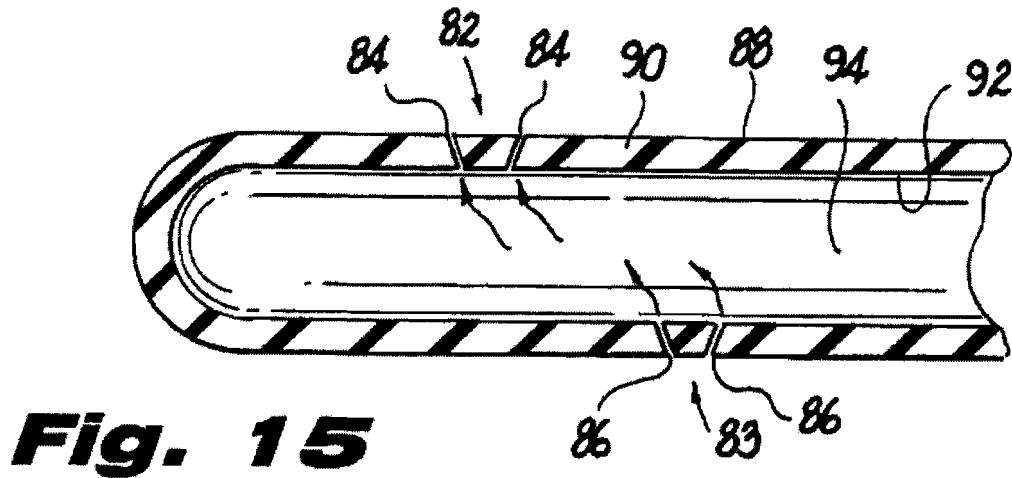
Examiner's assertion that opening 40 of Alchas is fully capable of all structural, functional, spatial and operation limitations associated with the claim language of "elongate guidewire port," this is clearly incorrect. For example, an elongate guidewire port is, at a minimum, elongate. This is clearly a structural or spatial limitation associated with the language "elongate guidewire port" that the circular opening 40 of Alchas is not capable of meeting. Appellant therefore respectfully asserts that all claim elements are not taught or suggested, contrary to the Examiner's assertion.

2. *There must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings.*

To establish *prima facie* obviousness of a claimed invention, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. *In re Kahn*, 441 F.3d 977, 986, 78 USPQ2d 1329, 1335 (Fed. Cir. 2006). The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990).

There is no motivation in the teachings of Alchas and Person et al. to make the claimed combination. The Examiner points out that Person et al. disclose an angled slit (82 and 84) and that "it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the sheath of Alchas with the angled slit as described by Person et al. for opening to increased pressure from the lumen of the catheter into the vessel in which the catheter is positioned (col. 5, lines 17-30)." Final Office Action of September 12, 2006 at page 3.

However, Person et al. are not here talking about *a slit* but about *a pair of slits* disposed on intersecting planes. The slits “are cut at an angle from the outer surface 88’ through wall 90’ to inner surface 92’ such that one of the slits 84’ is cut in the direction towards the other slit 84’ ” and “intersect interiorly within the catheter 80 within lumen 94.” Person et al., column 5, lines 22-26. Because the pair of slits are cut in this manner, the valve 82’ which is formed from the slits “opens outwardly in response to increased pressure from the lumen 94 to permit for infusion of fluids from the lumen 94 of the catheter.” Person et al., column 5, lines 27-29. The next paragraph in the specification describes valve 83’ in which a pair of slits are configured in an opposite configuration. Person et al., column 5, lines 31-39. Valves 82’ and 83’ are shown in Figure 15:



The final paragraph describing the embodiment of Figure 15 describes how pressure in the lumen seals valve 83 and how a decrease of pressure in the lumen seals valve 82. Person et al. are describing a pair of one-way valves, each of which is made from a pair angled slits in the catheter wall. Thus the motivation described by the Examiner is applicable only to a pair of slits. Person et al. are silent with regard to a single angled slit - what one would do with it or why one might make it. Thus the motivation that the Examiner cites, which describes the operation of a

pairs of slits, is not applicable to a single slit and therefore does not constitute a motivation to angle a single slit. Appellant therefore respectfully submits that there is no motivation to modify Alchas in view of Person et al.

A further deficiency in the *prima facie* rejection is proposed motivation for modifying the modified catheter to align the slit with the longitudinal axis of the shaft. The Examiner asserts that it would have been obvious to make the slit parallel to the longitudinal axis, first saying that “it would have been an obvious matter of design choice to position the slit parallel along the longitudinal axis, since applicant has not disclosed that the parallel slit over the angled slit solves any stated problem or is for any particular purpose,” and then saying that “in the alternative one of ordinary skill in the art would have made a modification to make the slit parallel to the longitudinal axis because it would be an obvious modification and it has been held that rearranging parts of an invention involves only routine skill in the art.” Final Office Action of September 12, 2005 at page 3. However, the fact that references can be modified or that a claimed invention is within the inventive capabilities of one of ordinary skill in the art is not sufficient by itself to establish *prima facie* obviousness. Moreover, “the mere fact that a worker in the art could rearrange the parts of the reference device to meet the terms of the claim on appeal is not by itself sufficient to support a finding of obviousness.” *Ex parte Chicago Rawhide Mfg. Co.*, 223 USPQ 351 (Bd. Pat. App. & Inter. 1984).

The claimed invention is not an obvious design choice over the cited references for at least the reason that Person et al. teach away from it. Person et al. teach “In each of the embodiments, it is preferred that the valves are positioned at an angle to the longitudinal axis of the catheter in an area of reduced thickness to increase the size of the opening for the ingress and egress of fluids.” Person et al., column 2, lines 30-34. A longitudinally aligned slot is therefore

not an obvious design choice over Person et al; such a modification would reduce the size of the opening for the ingress and egress of fluids. The catheters of both Person et al. and Alchas are used for fluid passage. The proposed modification, which has been criticized by Person et al., would therefore, according to Person et al., make the proposed catheter less suitable for its intended use. Because the proposed modification has been criticized by Person et al., one cannot say that it is an obvious matter of design choice or a mere matter of rearranging the parts. Appellant therefore submits that there is no motivation to modify the catheter so that the slit is parallel to the longitudinal axis of the shaft.

Therefore, there is no motivation to combine the teachings of Alchas with the teachings of Person et al. The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990). The Examiner has failed to establish any motivation to combine Person et al with Alchas and has for this reason not established a *prima facie* case of obviousness. Therefore, claims 13 and 15-17 are believed to be allowable over Alchas in view of Person et al.

3. Conclusion.

Because all the claim elements are not taught or suggested by the cited prior art and because there is no motivation to combine the references in the manner suggested by the Examiner to produce the claimed catheter, the Examiner has failed to establish a *prima facie* case of obviousness. As such, claims 13 and 15-17 are believed to be allowable over Alchas in view of Person et al.

B. CONCLUSION.

For the reasons stated above, claims 13 and 15-17 are believed to be allowable over Alchas in view of Person et al., and the Examiner's rejections of these claims under 35 U.S.C. § 103(a) should be overruled.

Respectfully submitted,

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VIII. CLAIMS APPENDIX

13. A single lumen microcatheter, comprising:

an elongate shaft having a distal end and a proximal end, the elongate shaft having an outer surface and an inner surface, the inner surface defining a lumen extending through the elongate shaft;

an elongate guidewire port positioned proximal of the distal end of the elongate shaft, the elongate guidewire port extending from the inner surface of the elongate shaft to the outer surface of the elongate shaft; and

a polymer sheath disposed over the elongate guidewire port, the polymer sheath having an inner surface and an outer surface, the polymer sheath including a passage comprising an angled slit extending radially through the polymer sheath at an angle such that the slit has a depth that is greater than a thickness of the polymer sheath, the slit disposed parallel to a longitudinal axis of the elongate shaft, the passage in communication with the elongate guidewire port, wherein the passage is configured to permit guidewire access through the elongate guidewire port while remaining substantially fluid tight in use when no guidewire is provided through the passage.

15. The single lumen microcatheter of claim 13, wherein the angled slit extends radially through the polymer sheath at an angle substantially less than 90 degrees to the outer surface of the polymer sheath.

16. The single lumen microcatheter of claim 13, wherein the angled slit extends from the outer surface of the polymer sheath to the inner surface of the polymer sheath.

17. The single lumen microcatheter of claim 13, wherein the angled slit is configured to accept both a guidewire and a sheath wherein the sheath is configured to accept the guidewire therein.

IX. EVIDENCE APPENDIX

No additional evidence has been presented.

X. RELATED PROCEEDINGS APPENDIX

None